JUL 3 2003

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SURGRX

510(k) SUMMARY

1. Submitter Name and Address

SurgRx, Inc.
380 Portage Avenue
Palo Alto, CA 94306
Contact: Linda Oleson
Phone: (650) 739-0920 xt 107
Date: 6/10/03

2. Device Name

Trade name: EnSeal Vessel Sealing & Hemostasis System

Common name: Electrosurgical open and laparoscopic instruments and accessories

Classification name: Electrosurgical Cutting and Coagulation Device and Accessories (per 21 CFR section 878.4400) and Gynecologic Electrocautery and Accessories (per 21 CFR 884.4120).

3. Predicate Device

ValleyLab LigaSure Vessel Sealing System (K981916).

4. Device Description

The EnSeal Laparoscopic devices are tubular instruments with grasping jaws at the distal end, which are actuated by a handle at the proximal end of the device. The distal end contains bipolar electrodes for sealing vessels, and a mechanical cutting blade for transecting vessels. The EnSeal Open devices are reusable forceps-type devices with one snap-in single use, disposable bipolar electrode, and one permanent, reusable electrode in the jaws of the device. Connectors attached to an electrical cable connect the device to the ECA (EnSeal Controller Adapter) accessory which connects the device to a standard O.R. electrosurgical generator.

5. Intended Use

The SurgRx EnSeal devices are intended for use during open or laparoscopic general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue and/or seal vessels during surgery. The SurgRx EnSeal Vessel Sealing & Hemostasis System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

6. Technological Characteristics

The EnSeal devices are similar to the predicate devices in that they are all bipolar instruments used to cut and seal vessels, grasp and dissect tissue, utilizing RF powered distal ends. They vary in technological characteristics by jaw design.

7. Performance Data

Preclinical laboratory (bench studies) and performance tests were executed to ensure the devices functioned as intended and met design specifications.

8. Conclusions

The EnSeal devices outperformed the predicate devices in comparative preclinical testing. Based on performance and functional similarities to the predicate devices, we believe the EnSeal devices are safe and effective and substantially equivalent to the predicate devices.

- Pacemakers and implanted cardioverter/defibrillators can be adversely affected by RF signals. Consult the pacemaker/cardioverter/defibrillator manufacturer for further information when use of electrosurgical equipment is planned in patients with these devices. If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer instructions before performing electrosurgery. This treatment may cause multiple activations of an ICD.
- SurgRx recommends against the use of laparoscopic surgery on pregnant patients.
- SurgRx recommends against the use of electrosurgery for circumcisions.
- The SurgRx EnSeal Vessel Sealing & Hemostasis System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

3. Engineering Specifications

See Attachment 4 for engineering drawings/physical descriptions of the devices and complete materials lists.

a) Components

Open Instruments

Reusable Handle :	Surgical stainless steel
Jaws (disposable and reusable portions):	Surgical stainless steel, carbon filled polyethylene, polyetherimide (Ultem), silicone, silicone coating.

Laparoscopic Instruments

Handle:	Acrylonitrile-butadiene-styrene Terpolymer (ABS)
Jaws:	Surgical stainless steel, carbon filled polyethylene, silicone coating.
I-Beam:	Surgical stainless steel
Shaft:	Surgical stainless steel, heat shrink insulation of polyolefin shrink tubing – black.

c) Human Factors

Instruments are designed similar to currently marketed devices. The device has been evaluated from the user perspective in pre-clinical and bench testing by physicians, and taken into consideration as design input. Devices should be easily adaptable to users.

d) Packaging

All SurgRx EnSeal products packaging shall conform to the International Safe Transit Association (Project 1A and Project 2A) requirements for packaged products weighing less than 100 pounds. Customer over shippers shall meet the following ASTM 4169-99 standards for: Impact Test Criteria, Static Compression Test Criteria, Vibration Test Criteria.

Laparoscopic devices will be packaged on a chip board tray in a Tyvek pouch for radiation sterilization, and placed in a chip board box. Six unit boxes will be packaged in a corrugated over shipper.

The non-sterile Open device handles will be packaged in a bubble-wrap pocket and placed in a corrugated cardboard box for shipping.

Disposable electrodes will be packaged in a Tyvek pouch for radiation sterilization and 12 unit pouches will be placed in a chipboard box.

The ECA box will be placed in an anti-static bag, surrounded by protective foam cushioning and placed in a corrugated box. ECA Accessories (batteries in a ziplock bag, footswitch in a ziplock bag, Reusable Extension Cable in a ziplock bag) will be placed in a packaging insert corrugated box and placed in the same box as the ECA (*see Attachment 4 for exploded view*).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2003

Surgrx, Inc.
c/o Mr. Morten Simon Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K031133
Trade/Device Name: SurgRx EnSeal Vessel Sealing & Hemostasis System
Regulation Number: 21 CFR 884.4120, 21 CFR 878.4400
Regulation Name: Gynecologic electrocautery and accessories
Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HGI
Dated: June 17, 2003
Received: June 19, 2003

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: SurgRx, Inc.

510(k) number (if known): K031133

Device Name: SurgRx EnSeal Vessel Sealing & Hemostasis System

Indications for Use:

The SurgRx EnSeal system includes bipolar electrosurgical instruments and an accessory adapter for use with standard electrosurgical generators. It is intended for use during open or laparoscopic, general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as will fit in the jaws of the instruments.

The SurgRx EnSeal Vessel Sealing & Hemostasis System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhe

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031133